UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,838	08/12/1998	OLEG LLIICH EPHSTEIN	841/3	4128

27538 7590 10/08/2008

KAPLAN GILMAN GIBSON & DERNIER L.L.P.
900 ROUTE 9 NORTH
WOODBRIDGE, NJ 07095

EXAMINER	
PESELEV, ELLI	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/117,838	EPHSTEIN, OLEG LLIICH	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008 and 10 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-21,23,25-27,29-34 and 38-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 19-21, 23, 25-27, 29-34 and 38-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is indefinite in that it depends from the cancelled claim 35.

Method claims 46-48 are indefinite in that the decease or condition being treated has not been set forth.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set f98orth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19-21, 23, 25-27 and 45-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said composition. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the

same chemical structure and combining said substances into a single composition would inherently result in the prior art's composition

Claims 29 and 38 are rejected under 35 U.S.C. 102((b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 3,901,967).

Cohen et al disclose a pharmaceutical comprising atropine sulfate. The claimed composition comprising atropine sulfate and a homeophatic dilution of atropine sulfate is inherent in the prior art's composition.

Claims 30 and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirany (U.S. Patent No. 4,987,127).

Sirany discloses a pharmaceutically composition comprising acetylsalicylic acid. The claimed composition comprising acetylsalicylic acid and a homeophatic dilution of acetylsalicylic acid is inherent in the prior art' composition.

Claims 31, 40 and 41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nobile (U.S. Patent No. 3,134,718).

Nobile discloses a pharmaceutical composition comprising Prednizolon. The claimed medication comprising prednizolone and a homeophatic dilution of Prenizolone is inherent in the prior art's composition.

Claims 32 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Massey (U.S. Patent No. 4,839,341).

Massey disclose a pharmaceutical composition of insulin. The claimed composition comprising insulin and a homeophatic dilution of insulin is inherent in the prior art's composition.

Claims 33 and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,342).

Jonsson et al disclose a pharmaceutical composition comprising zinc. The claimed composition comprising zinc and a homeophatic dilution of zinc in inherent in the prior art's composition.

Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Albert Stock John et al (U.S. Patent No. 3,032,584).

Albert Stock John et al disclose a pharmaceutical composition comprising Sarcolysin. The claimed composition comprising Sarcolysin and a homeophatic dilition of Sarcolysin, is inherent in the prior art's composition.

Applicant's arguments filed August 1, 2008 and September 10, 2008 have been fully considered but they are not persuasive.

Applicant contends that a therapeutic medicine and a homeophatic dilution of said medicine are not the same. This argument gas not been found persuasive since applicant has not pointed out how the structural formula of a

therapeutic medicine differs from the structural formula of a homeophatic dilution of said medicine. The claimed composition encompass nothing more than combining the same medicine in different concentration resulting in medicine which is patentably indistinguishable from the conventional medicine disclosed in the prior art of record.

Applicant further contends that the prior art of record does not disclose a therapeutically active compound that "possess enhanced therapeutic properties in comparison with said active medicine alone". This argument has not been found persuasive since applicant has not presented data comparing the claimed composition with the prior art's composition which is commensurate in scope with the claimed invention.

The declaration of Dr. Epstein filed 2/8/2008 has been considered.

The declaration does not present data relating to atropine sulfate, acetylsalicylic acid , insulin, zinc and sarcolysin encompassed by the present claims.

With respect to prednisolone, the declaration states that the combined administration of ultra low dose of prednisolone and prednisolone resulted in reduction of side effects. However, it is not clear from said statement the number of subjects treated and it is not clear from said statement the dosage of prednisolone itself administered. Therefore, the significance f the results presented cannot be ascertained.

It is still unclear how a ultra low dose of a medicine combined with the prior's medicine results in a different medicine being produced.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623